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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,427	02/28/2002	Carl Johan Friddle	LEX-0313-USA	6370

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EXAMINER	
GAMETT, DANIEL C	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,427	FRIDDLE ET AL.	
	Examiner	Art Unit	
	Daniel C. Gamett, PhD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendments of 12/05/2005 have been entered in full. Claims 1-7 are under examination. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Claim Rejections - 35 USC § 101

3. Claims 1-7 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility. Applicant's arguments filed 12/05/2005 have been fully considered but they are not persuasive.

4. A patent application does not satisfy utility requirement of 35 U.S.C. §101 unless it discloses both "substantial" utility for claimed invention, in form of significant and presently available benefit to public, as well as "specific" utility, which is well-defined and particular benefit to public, *In re Fisher*, 76 USPQ2d 1225 (CA FC 2005). In *Fisher*, the court supported the BPAI in finding that there is a difference between a substantial utility, which satisfies the utility requirement of §101, and an insubstantial utility, which fails to satisfy §101. The rejection of record addressed assertions made in the specification that the invention can be used for a variety of diagnostic and therapeutic purposes. The rejection was not based on an alleged requirement for FDA approval. The rejection made no mention of safety or efficacy of any diagnostic or treatment method based on the claimed nucleic acid. The rejection states that these asserted utilities are not specific or substantial, because there is no nexus between the specific

claimed sequence and a physiological process or disease state. This is not altered by the knowledge that the claimed sequence is a variant of semaphorin 6D, as shown in Exhibits A and B. Semaphorin 6D cannot be used to diagnose or treat any disease, nor has any nexus between semaphoring 6D and a specific physiological process or disease state been established.

5. The Qu *et al.* reference (Exhibit C) does not establish a specific or substantial utility, it merely indicates that the community of basic researchers agreed that the gene was worthy of study. The conclusions of the Qu *et al.* paper show that, at the time of filing, a substantial utility had not been established for the gene. In the paragraph bridging pages 35583-35584, Qu *et al.* compared semaphorin 6A to "another "function unknown" semaphorin, SEMA6B" and, referring to the tissue distribution of gene expression, stated, "This profile is consistent with a more general role of the proteins in neurogenesis and organogenesis as well as in regenerative and degenerative processes...it is likely that many of these overlapping molecules have redundant functions acting on any class of axons, but their probable precise combinations guiding many classes of axons, by process of elimination, to their target tissues need to be revealed". The concluding sentence of Qu *et al.* states, "It is hoped that the characterization of the receptors for SEMA6C and SEMA6D and the further elucidation of their functions *in vivo* will facilitate the understanding of the mechanism of neural development and nerve regeneration after injury and provide us with possible treatment strategies for certain neurodegenerative diseases." Therefore, the Qu *et al.* reference supports the point made in the rejection of record, "while semaphorins are interesting and important from the point of view of basic biology, assignment of a new sequence to the family of semaphorins does not indicate a well established, patentable utility."

6. Applicant (response, pages 8-10) has presented a compelling argument for a real world utility for gene chips, but this argument is not on target for the nucleic acid sequence in question. Applicant asserts that the claimed nucleic acid would enhance the utility of a gene chip. In general, adding more sequences to a chip should make the chip more informative. The question is whether addition of the claimed sequence enhances the value of the information gained from the chip in a specific and substantial way. At the time of filing, any result obtained from use of the claimed nucleic acid on a chip would have been interpreted as a step in the characterization of the gene itself.

7. The "gene mapping" utility argued in page 11 of the response is similarly non-specific. In general, genetic maps based on nucleic acid sequences have higher resolution than maps provided by Giemsa staining. At the time of filing, a genetic map obtained from use of the claimed nucleic acid would have been a step in the characterization of the gene itself. Likewise, any coding sequence can be used to identify exons and splice junctions, so these utilities are not specific. Presently, the exons, polymorphisms, and splice variants that have yet to be discovered have no patentable utility, so searching for them cannot be a patentable utility.

8. Therefore, both the gene chip and mapping utilities are examples of "use testing", which is not a patentable utility (*Brenner v. Manson*, 148 USPQ at 696). See also Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct, 1966), wherein the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

9. The possibility that patents have been issued wherein the claimed nucleic acids fail to meet the published Utility Guidelines (Response, pages 13-15) is not relevant to the matter at hand; each case must be decided on its own merits. Based on the totality of evidence, it is proper that the rejection of record be maintained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D.,whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DCG
Art Unit 1647
22 February 2006

DAVID S. ROMEO
PRIMARY EXAMINER